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CHAKRABARTI,A	
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Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/669,301	Applicant(s) Kudlicki
	Examiner Arun Chakrabarti	Art Unit 1655

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 9/25/00, 11/19/00, 1/23/01, 5/7/01, 10/9/01, and 10/18/01 .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-23 and 37-49 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-23 and 37-49 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 and 6
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election /Restriction

1. Applicant has elected Group I corresponding to claims 1-23 and 37-49 without traverse, in paper number 7.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6, 11, 16, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is rejected over the recitation of the phrase , "composition is further defined as an in vitro translation reaction". It is not clear how a composition can be equivalent to a reaction. Composition is usually used to carry out a reaction. It is not clear if the composition of the method is claimed or the reaction of the method is claimed or both are claimed. The metes and bounds of the claim is vague and indefinite. The language, "composition is used in an in vitro translation reaction" is suggested.

Regarding claims 11, 16 and 14, the phrase "capable of" renders the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 7, 20, and 23 are rejected under 35 U.S.C. 102 (b) as being anticipated by Lee et al. (Immunochemistry, (1972), Vol. 9, pages 210-213).

Lee et al teach a method comprising:

a) obtaining at least a first nuclease inhibitor (Page 211, MATERIALS AND METHODS Section, Isolation of polysome fractions Subsection, line 4, Magnesium Chloride in this case);

b) obtaining at least a second nuclease inhibitor (Page 211, MATERIALS AND METHODS Section, Isolation of polysome fractions Subsection, lines 4-5, heparin in this case); and

c) obtaining a composition (Page 211, MATERIALS AND METHODS Section, Isolation of polysome fractions Subsection, lines 1-5, rabbit spleen tissue in phosphate buffered saline in this case); and

d) admixing the nuclease inhibitors and the composition (Page 211, MATERIALS AND METHODS Section, Isolation of polysome fractions Subsection, lines 1-10).

Lee et al teach the method, wherein admixing is carried out by mixing the first and second nuclease inhibitors to form a nuclease inhibitor cocktail and mixing the nuclease inhibitor cocktail with the composition (Page 211, MATERIALS AND METHODS Section, Isolation of polysome fractions Subsection, lines 1-10).

Lee et al teach the method, wherein obtaining the first and second nuclease inhibitors comprises obtaining a nuclease inhibitor cocktail comprising the first and second nuclease inhibitor (Page 211, MATERIALS AND METHODS Section, Isolation of polysome fractions Subsection, lines 4-5, Magnesium Chloride and heparin in this case).

Lee et al inherently teach the method, wherein the composition comprises at least one nuclease and RNA (Page 211, MATERIALS AND METHODS Section, Isolation of polysome fractions Subsection, lines 1-10). This inherence is deduced from the fact that a freshly excised rabbit spleen naturally contains several nuclease and RNA.

Lee et al inherently teach the method, wherein the composition is a reagent used in molecular biology (MATERIALS AND METHODS Section, and RESULTS AND DISCUSSION Section). This inherence is deduced from the fact that polyribosomes (site of protein synthesis in cells) isolation is essentially under the domain of molecular biology.

Lee et al teach the method, wherein the second nuclease inhibitor is heparin (Page 211, MATERIALS AND METHODS Section, Isolation of polysome fractions Subsection, lines 4-5,)

Lee et al teach the method, further defined as a method of inhibiting nucleases in the composition (Page 211, lines 2-3 and MATERIALS AND METHODS Section, and RESULTS AND DISCUSSION Section).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-5, 7-11, 20, 22 and 23 are rejected under 35 U.S.C. 103 (a) over Lee et al. (Immunochemistry, (1972), Vol. 9, pages 210-213).

Lee et al teach method of claims 1-5, 7, 20, and 23 as described above.

Lee et al teach the method, wherein the second nuclease inhibitor is a polyclonal anti-ribonuclease antibody and capable of binding to mRNA ribonuclease (Figure 1 and

MATERIALS AND METHODS Section, second paragraph, and Introduction, Second paragraph, first five lines) and the first nuclease inhibitor is Magnesium chloride .

Lee et al do not teach the method, wherein the first nuclease inhibitor is an anti-nuclease antibody.

It would have been prima facie obvious to an ordinary practitioner to switch the order of selecting the inhibitors of nuclease as MPEP 2144.04 further states, " *In re Gibson,* 39 F.2d 975, 5 USPQ 230 (CCPA 1930) Selection of any order of mixing ingredients is *prima facie* obvious"

8. Claims 1-5, 7-12, 20, 22, and 23 are rejected under 35 U.S.C. 103(a) over Lee et al. (Immunochemistry, (1972), Vol. 9, pages 210-213) in view of Bucala et al. (U.S. Patent 6,110,968) (August 29, 2000).

Lee et al teach method of claims 1-5, 7-11, 20, 22 and 23 as described above.

Lee et al do not teach the method, wherein the anti-ribonuclease antibody is an anti-RNAse A antibody.

Bucala et al. teach the method, wherein the anti-ribonuclease antibody is an anti-RNAse A antibody (Column 11, lines 14-18).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine, within the method of inhibiting the nuclease of Lee et al., an anti-RNAse A antibody of Bucala et al. since Bucala et al state, "To assess the formation of dimers, the samples were subjected to SDS-PAGE under reducing conditions, followed by transfer to cellulose and western blotting with a rabbit anit-RNAse A antibody

(Column 11, lines 14-17)". Moreover Lee et al provides further motivation as Lee et al state, "On the basis of this explanation, it may be suggested that the procedure for isolation of polysomes could be further improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract (Page 212, last sentence to page 213, line 1)". By employing scientific reasoning, an ordinary artisan would have been motivated by the express statement of Bucala et al to substitute and combine, within the method of inhibiting the nuclease of Lee et al., an anti-RNAse A antibody of Bucala et al. in order to achieve the express advantages, as noted by Bucala et al. , of a method which provides the assessment of the formation of dimers between antigen and antibody and also to achieve the express advantages, as noted by Lee et al. , of a strategy which provides the procedure for isolation of polysomes that could be further improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract.

9. Claims 1-5, 7-11, 13, 14- 20, 22, and 23 are rejected under 35 U.S.C. 103(a) over Lee et al. (Immunochemistry, (1972), Vol. 9, pages 210-213) in view of Cazenave (Proceedings of the National Academy of Sciences (USA), (1977), Vol. 74 (11), pages 5122-5125).

Lee et al teach method of claims 1-5, 7-11, 20, 22 and 23 as described above.

Lee et al do not teach the method, wherein the anti-ribonuclease antibody is an anti-RNAse 1 antibody.

Cazenave teaches the method, wherein the anti-ribonuclease antibody is an anti-RNAse 1 antibody (Abstract).

Lee et al do not teach the method, wherein the anti-ribonuclease antibody is an anti-RNAse T1 antibody and anti-deoxyribonuclease antibody.

Lee et al suggest the method, wherein the anti-ribonuclease antibody is against all other nuclease present in the crude tissue (Page 212, last sentence to page 213, line 1).

Lee et al do not teach the method, wherein the anti-ribonuclease antibody is capable of binding to micrococcal nuclease.

Cazenave teaches the method, wherein the anti-ribonuclease antibody is capable of binding to micrococcal nuclease (Page 5124, Column 1, second paragraph).

Lee et al do not teach the method, wherein the second and third nuclease inhibitor are anti-ribonuclease antibody.

Cazenave teaches the method, wherein the equivalent second and third nuclease inhibitor are anti-ribonuclease antibody. (Abstract and MATERIALS AND METHODS Section).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine, within the method of inhibiting the nuclease of Lee et al., mixtures of anti-RNAse 1 antibodies of Cazenave since Lee et al state, "On the basis of this explanation, it may be suggested that the procedure for isolation of polysomes could be further improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract (Page 212, last

sentence to page 213, line 1)". By employing scientific reasoning, an ordinary artisan would have been motivated by the express statement of Lee et al to substitute and combine, within the method of inhibiting the nuclease of Lee et al., mixtures of anti-RNAse 1 antibodies of Cazenave in order to achieve the express advantages, as noted by Lee et al. , of a strategy which provides the procedure for isolation of polysomes that could be further improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract.

10. Claims 1-5, 6-11, 20- 23, and 37-49 are rejected under 35 U.S.C. 103(a) over Lee et al. (Immunochemistry, (1972), Vol. 9, pages 210-213) in view of Murphy et al. (BioTechnique, (1995), Vol. 18(6), pages 1069-1073).

Lee et al teach method of claims 1-5, 7-11, 20, 22 and 23 as described above.

Lee et al do not teach the method, wherein the composition is further defined as a transcription/translation reaction comprising both DNA and RNA.

Murphy et al. teach the method, wherein the composition is further defined as a transcription/translation reaction comprising both DNA and RNA.. (Abstract and MATERIALS AND METHODS Section, In vitro transcription and translation Subsection and cDNA synthesis Subsection, Page 1069).

Lee et al do not teach the method, wherein the nuclease inhibitor is human placental ribonuclease inhibitor.

Murphy et al. teach the method, wherein the nuclease inhibitor is human placental ribonuclease inhibitor (Introduction Section, Column 1, last sentence).

Lee et al do not teach the method, wherein the anti-ribonuclease antibody is capable of binding to S1 nuclease and anti-deoxyribonuclease antibody.

Lee et al suggest the method, wherein the anti-ribonuclease antibody is against all other nuclease present in the crude tissue (Page 212, last sentence to page 213, line 1).

Lee et al do not teach the method, wherein the nuclease inhibitor cocktail and a lysate are placed in the in vitro translation reaction.

Murphy et al. teach the method, wherein the nuclease inhibitor cocktail and a lysate are placed in the in vitro translation reaction. (Abstract and MATERIALS AND METHODS Section, In vitro transcription and translation Subsection, Page 1069).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine, within the method of inhibiting the nuclease of Lee et al.,the nuclease inhibitor cocktail and a lysate placed in the in vitro translation reaction. of Murphy et al. since Murphy et al state, "It has a high specific activity, enhanced temperature stability, broad reaction pH range and significantly greater cost-effectiveness than commercial HPRI. Prime inhibitor is suitable for use in in vitro transcription, in vitro translation, first and second-strand cDNA synthesis, preparation of RNA and mRNA, and reverse transcription polymerase chain reaction (Abstract, last two sentences)". Moreover, Lee et al state, "On the basis of this explanation, it may be suggested that the procedure for isolation of

polysomes could be further improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract (Page 212, last sentence to page 213, line 1)". By employing scientific reasoning, an ordinary artisan would have been motivated by the express statement of Murphy et al to substitute and combine, within the method of inhibiting the nuclease of Lee et al., the nuclease inhibitor cocktail and a lysate placed in the in vitro translation reaction. of Murphy et al. in order to achieve the express advantages, as noted by Murphy et al. , of inhibitors which has a high specific activity, enhanced temperature stability, broad reaction pH range and significantly greater cost-effectiveness than commercial HPRI and which is suitable for use in in vitro transcription, in vitro translation, first and second-strand cDNA synthesis, preparation of RNA and mRNA, and reverse transcription polymerase chain reaction, and also in order to achieve the express advantages, as noted by Lee et al. , of a strategy which provides the procedure for isolation of polysomes that could be further improved by the use of polyspecific immunosorbents prepared with antibodies elicited against r-s-RNase and all other nucleases present in the crude tissue extract.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti , Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0195.

Arun kr. Chakrabarti

Arun Chakrabarti,

Patent Examiner,

October 30, 2001